

CONTRACEPTION: SIDE EFFECTS

Kiranpreet Chawla, MD FACOG

Assistant Professor of Obstetrics, Gynecology, & Reproductive Sciences

University of Maryland

FINANCIAL DISCLOSURES

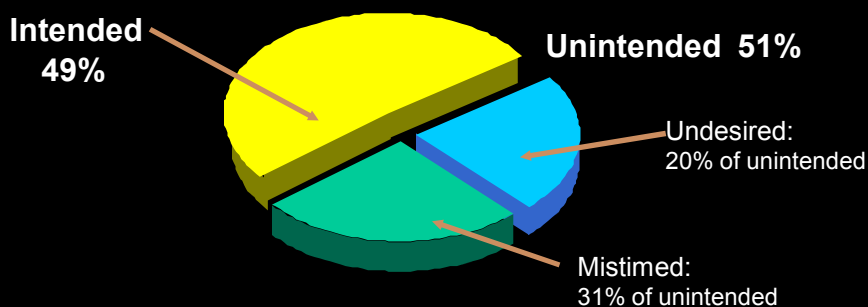
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LEARNING OBJECTIVES

- Manage common side effects of contraception.
 - Evaluate patients to help them select a contraceptive method that will maximize correct use and continuation.
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UNINTENDED PREGNANCY

3.4 million unintended pregnancies per year in the U.S.



54% of women having abortions report using contraception in the month they became pregnant

Finer LB, et al. American Journal of Public Health, 2014; 104(S1): S44-S48

CDC: MEDICAL ELIGIBILITY CRITERIA

Systematic review of evidence – Released 2010

- 1 → No restriction for use of the method
 - 2 → Advantages of using the method generally outweigh the theoretical or proven risks
 - 3 → Theoretical or proven risks usually outweigh the advantages of using the method
 - 4 → An unacceptable health risk if the contraceptive method is used
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CASE 1

- 25yo g7p2052 presents with a nexplanon in place for 6 months. Pt is very happy with the nexplanon, but is very frustrated with her irregular bleeding. She states that she bleeds from 3-25 days every month since placement and that it can be as light as a spotting to as heavy as a full menstrual flow. It is unpredictable. How would you manage this patient?
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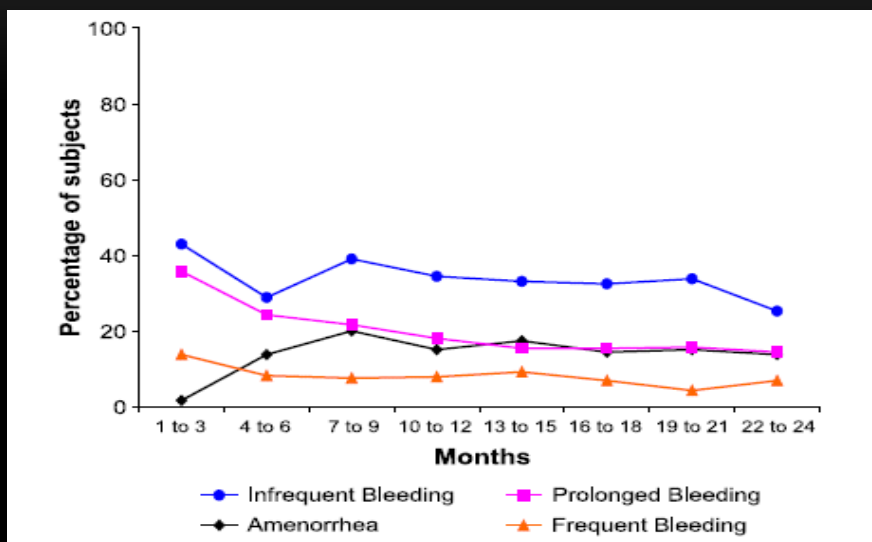
ETONOGESTREL IMPLANT BLEEDING PATTERNS



- Total number of bleeding/spotting days decreased or similar for majority of users
- Key difference:
 - irregularity and unpredictability
- ~20% amenorrhea in 1st year
 - Increases to 30-40% after 1st year

Mansour et al. Eur J Contr Reprod Health Care 2008;13S1:13

ETONOGESTREL IMPLANT BLEEDING PATTERNS



Funk et al. Contraception 2005;71:319.

MANAGEMENT OF BLEEDING

Table 3

A pragmatic approach to the use of currently available therapies in stopping unscheduled bleeding in users of ENG contraceptive implant

| | Therapy regimen | Supportive evidence |
|---------------|---|--|
| First choice | COC taken daily for 21 days followed by a 7-day break. Use for up to three months. | Little published evidence. Anecdotally, appears to help in practice |
| Second choice | High-dose cyclical progestogen for up to 3 months (medroxyprogesterone acetate 10 mg twice daily or norethisterone 5 mg twice daily for 21 days with a 7-day break) | No published evidence. Anecdotally, appears to help in practice |
| Third choice | POP, particularly a desogestrel POP, taken daily for up to three months | No published evidence. Anecdotally, may work in some cases |
| Fourth choice | NSAIDS, especially COX-2 inhibitors, taken daily for 5-10 days | Some published evidence. Anecdotally, may work in practice |
| Fifth choice | Tranexamic acid 500 mg twice daily for 5 days | Limited published evidence. Anecdotally, may work in practice |

Mansour et al. Contraception 2011;83:202

MANAGEMENT OF BLEEDING

1st Choice

Daily COC for 21 days, followed by 7-day break.
Use for up to 3 months.

Newer Choice studied

Doxycycline 100mg twice daily for 7 days.

(norethisterone 5 mg twice daily for 21 days with a 7-day break)

2nd Choice

High-dose progestin for 21 days with 7-day break
(e.g. medroxyprogesterone acetate 10mg twice daily).
Use for up to 3 months.

Mansour et al. Contraception 2011;83:202

OTHER SIDE EFFECTS



- Acne
 - 17% reported acne
 - 1.3% of women discontinued for acne
 - 61% of women with acne at baseline reported improvement, and only 8% worsened
-

Funk et al. Contraception 2005;71:319.

OTHER SIDE EFFECTS



- Weight gain
 - Overall increase in BMI 0.7kg/m²
 - Not a significant increase
 - 12.7% of women reported weight gain
 - 3.3% of women discontinued for weight gain
-

Funk et al. Contraception 2005;71:319.

EFFICACY IN OVERWEIGHT WOMEN



- No clinical trial data
 - Women >130% ideal body weight excluded
 - Only total of 134 women > 70kg: no failures
- Small pharmacokinetics study indicates *projection* of hormone levels sufficient to inhibit ovulation
- Not contraindicated in obese women or girls

Gilliam et al. Contraception. 2011;published abstract
Edelman A. SFP Guidelines. Contraception 2009;80:583.

VERY FEW CONTRAINDICATIONS

- SLE with anti-phospholipid antibodies
- Breast Cancer
- Hepatocellular adenoma
- Discontinue if develops during use:
 - Migraines with aura
- Unexplained vaginal bleeding suspicious for serious condition, before evaluation

CASE 2

- 24yo g1p1 presents to you with some concerns. She has been on depoprovera since the birth of her child (at the age of 19). She is very happy with this form of birth control but is concerned about what she read on the package labeling. How would you counsel this patient?
-

FDA BLACK BOX WARNING

Women who use Depo-Provera Contraceptive Injection may have a greater risk of developing osteoporosis and fractures.

It is unknown if the Depo-Provera Contraceptive Injection increases the risk of osteoporosis and fractures.

Depo-Provera Contraceptive Injection should not be used for a long time (see V).

1

DMPA & BONE MINERAL DENSITY (BMD)

- Use of DMPA is associated with loss of BMD
- After stopping, recovery of BMD is seen
 - return to baseline in 1-4 years
- No data on fracture risk in women who have used DMPA in the past

Berenson et al. Obstet Gynecol 2004;103
 Scholes et al. Arch Pediatr Adolesc Med 2005;159:139
 Harel et al. Contraception 2010;81:281

Slide 20

- 1 need to cite kaunitz
Melissa Gilliam, 2/23/2011

DMPA AND BMD

- Position papers:
 - WHO¹
 - ACOG²
 - Society of Adolescent Medicine³
- NONE recommend restricted initiation or continuation
- NONE recommend routine BMD testing

1 WHO Epidemiological Record No. 35, 2005

2 ACOG Practice Bulletin No. 73, 2006

3 Cromer BA et al. J Adolesc Health 2006;39:296

DEPO-PROVERA FEW CONTRAINDICATIONS

- Similar to progestin implant
- Severe hypertension ($\geq 160/\geq 100$)
- Diabetes *with*
 - vascular disease and / or
 - > 20 years disease

CASE 3

- 33yo g2p2002 with a PMHx sig for smoking has been on COC since delivery of her last child 3 years ago. Specifically she is on Levora (levonorgestrel/ethinyl estradiol 0.15/30). She really likes the pills, but has been dealing with random spotting and bleeding all through the month. It always worsens twds the end of her cycle. How would you manage this patient?
-

BREAKTHROUGH BLEEDING

- Common reason for discontinuation
- With time, improved with extended regimens
- Higher rates in women
 - who smoke
 - with cervical infections
 - Levonorgesterel containing forms
- Management:
 - If near end of cycle, discontinue early
 - If severe, consider exogenous estrogen

OTHER COMMON SIDE EFFECTS/CONCERNS

- Menstrual regulation
 - Acne
 - Weight Gain
 - VTE risk
-

ACNE

- All pills studied reduced acne compared to placebo
- No consistent results regarding different types of progestins
 - Cyproterone (pregnane) may be better than LNG
 - LNG may be better than desogestrel (!)


Arowojolu et al. *Cochrane Database of Systematic Reviews* 2009, Issue 3. Art. No.: CD004425. DOI: 10.1002/14651858.CD004425.pub4

WEIGHT AND COMBINED HORMONAL CONTRACEPTIVES

- CHC and Weight gain – NO LINK

Gallo et al. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD003987. DOI: 10.1002/14651858.CD003987.pub3.




WEIGHT AND CONTRACEPTIVE EFFICACY

| | Decreased Efficacy | NO EFFECT | Limited data |
|-------------------|---|-----------|--------------|
| Pill |  | | |
| Injectable |  | | |

Holt et al. Obstet Gynecol 2002. Women in the highest body weight quartile (70.5 kg or more) had a significantly increased risk of OC failure (RR 1.6, 95% CI 1.1, 2.4) compared with women of lower weight. (controlled for parity)

SFP Guidelines. Contraception 2009.

WEIGHT AND CONTRACEPTIVE EFFICACY

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| Injectable | |  | |

Brunner et al. Am J Epidemiol 2007. NSFG Analysis. No effect of weight on OCP effectiveness when controlled for age, parity, race.

SFP Guidelines. Contraception 2009.

WEIGHT AND CONTRACEPTIVE EFFICACY

| | Decreased Efficacy | NO EFFECT | Limited data |
|--------------|--------------------|-----------|--------------|
| Pill | ↓ | ⊘ | |
| Patch | ↓ | | |
| Ring | | | |

Zieman et al. Fertil Steril 2002. 5 of 15 pregnancies in 3 clinical trials occurred in the 3% of women > 90kg. [abstract]

SFP Guidelines. Contraception 2009.

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| Patch | ↓ | | |
| Ring | | ⊘ | |

Westhoff et al. Obstet Gynecol 2005. No effect of weight on efficacy of NuvaRing. [abstract only]

SFP Guidelines. Contraception 2009.

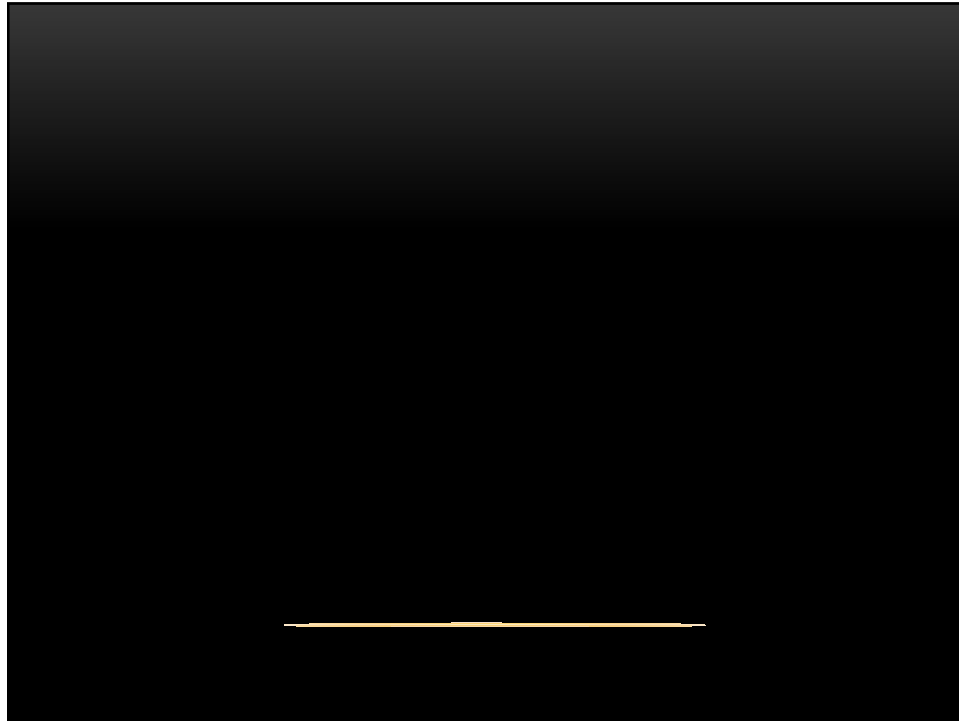
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| Patch | ↓ | | ✓ |
| Ring | | ⊘ | ✓ |

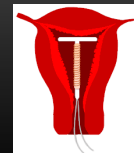
SFP Guidelines. Contraception 2009.

CASE 4

- 18 yo g0p0 with a PMH sig for Gonorrhea at age 17 s/p treatment presenting for contraception. Pt has done some research and would like an IUD. Pt primary provider stated she cannot get one because she has never had a child and has a history of gonorrhea. Thoughts?



INCREASING IUD USE AMONG YOUNG WOMEN



- 2008: current IUD use
 - 3.6% of contraceptors aged 15-19 years
 - from 0% in 2002
 - 5.9% of 20-24 year olds
 - from 1.8% in 2002
- ACOG Committee Opinion December 2007
 - IUDs should be offered as a “first-line choice” for contraception in both nulliparous and parous adolescents

Mosher et al. National Center for Health Statistics. Vital Health Stat 2010;23(29)

RISKS – YOUNGER PATIENTS



- Insertion may be more difficult in nulliparous women
- Higher expulsion in adolescents
- May have higher rates of copper IUD removals due to bleeding and pain
 - No evidence this occurs with the LNG-IUS

Deans et al. Contraception 2009
 Behringer et al. Contraception 2011;84:e5
 Hubacher D. Contraception 2007;75:S8

IUD AND PELVIC INFLAMMATORY DISEASE RISK EVIDENCE-BASED?

- Re-analysis excluding the Dalkon Shield and addressing bias = no increased risk
- 3 types of bias in observational studies:
 - Inappropriate comparison groups
 - Over diagnosis of PID among IUD users
 - Inability to control for confounding factors
- WHO analysis of 22,900 women over 8 yrs
 - Increased risk in first 20 days after insertion
 - No increased risk with continued use

Grimes D. Lancet 2000;356:1013
 Farley TM, Lancet 1992;339: 785

IUD CANDIDATES

- Prior STI or PID: NOT a contraindication
 - Contraindicated: current PID or within the past 3 months / Current cervicitis
- High risk women: screen for infection with GC or CT prior to insertion
- Adolescence and nulliparity are not contraindications
 - CDC category 2 for age < 20 years & nulliparity

CDC: U.S. Medical Eligibility Criteria for Contraceptive Use. May 2010.